

REMARKS

This is a full and timely response to the non-final Office Action mailed September 25, 2007. The Examiner is thanked for the thorough examination of the present application. Upon entry of this response, claims 1-3, 5-14, and 20 are pending in the present application. Claims 1-3, 5-8, 10-14, and 20-21 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Brunken (European Patent No. 0 615 726 A1). Claims 1 and 11 are also rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Matsutani, et al. (U.S. Pat. No. 4,935,029, hereinafter Matsutani). Claim 9 is rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Brunken in view of Anis (U.S. Pat. No. 5,352,233). Applicant respectfully requests consideration of the following amendments and remarks contained herein. Reconsideration and allowance of the application and presently pending claims are respectfully requested.

I. Oath/Declaration

The Office Action indicates that the oath/declaration is defective. In particular, the Office Action alleges that the oath/declaration *"does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56."* (Office Action, page 2). As an initial matter, Applicant questions why the Examiner did not allege this earlier in prosecution and submits that the Examiner should have noted this (alleged) deficiency back in the first Office Action (See MPEP 602.03: "In the first Office action the examiner must point out every deficiency in a declaration or oath and require that the same be remedied.")

Furthermore, Applicant disagrees that the oath/declaration submitted by the Applicant does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability. Applicant refers the Examiner to the following language in the oath/declaration that was submitted to the USPTO on October 29, 2003:

"I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, § 1.56."

While the Examiner points out that the language in Applicant's oath/declaration does not recite 37 CFR §1.56 verbatim ("material to the examination of this application" vs. "material to patentability"), Applicant submits that from a substantive standpoint, the oath/declaration acknowledges the Applicant's duty and furthermore, was made with specific reference to 37 CFR §1.56. Accordingly, Applicant submits that the oath/declaration is not defective.

II. Response to Claim Rejections Under 35 U.S.C. § 102

It is axiomatic that "[a]nticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." *W. L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554, 220 USPQ 303, 313 (Fed. Cir. 1983). Therefore, every claimed feature of the claimed invention must be represented in the applied reference to constitute a proper rejection under 35 U.S.C. § 102.

Claims 1-3, 5-8, 10-14, and 20-21 have been rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Brunken. Claims 1 and 11 have also been rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Matsutani. For at least the reasons set forth below, Applicant traverses these rejections.

Independent Claim 1 is Patentable Over Brunken

Claim 1, as amended, recites (emphasis added):

1. A suture needle comprising:
a shaft and a puncture tip at one end of a curve of the shaft,
wherein the shaft is marked with a visual indicator
which defines at least one of a front surface and a rear
surface, and
wherein the front surface and the rear surface extend side-
by-side along the shaft.

In the "Response to Arguments" section, the Office Action states the following:

"Applicant argues that Brunken does not teach a suture needle with two surfaces that extend side-by-side along at least a portion of the shaft. This is not convincing because the front and rear portions disclosed clearly extend side by side along the entire length of the shaft (see Figure 1)."

Applicant has amended claim 1 in an effort to further define certain novel features. Claim 1, as amended, now recites: "wherein the shaft is marked with a visual indicator which defines at least one of a front surface and a rear surface." Furthermore,

claim 1 recites the limitation, "wherein the front surface and the rear surface extend side-by-side along the shaft." Applicant respectfully submits that Brunken fails to teach these limitations. At most, the Brunken reference teaches the following (emphasis added):

[T]he surface of the puncture tip and of the zone of the needle adjoining same consists of bare or untreated metal, while the surface of the remaining section of the needle, which can account for up to ca. 50% of the needle length, is matt-finished or coloured.

(Page 3, lines 29-31). Unlike the Brunken reference, the present invention is comprised of a visually distinct front and rear surface that extend side-by-side along the shaft whereby the visual indicator differentiates between the two surfaces. Applicant maintains that Brunken instead teaches of different zones or sections and fails to teach a suture needle comprised of two surfaces that extend side-by-side along the shaft. The first zone/section consists of bare or untreated metal, while the surface of the remaining section of the needle is matt-finished or coloured. This is clearly depicted in FIG.1 of the Brunken reference.

Applicant, in fact, points out that the Office Action asserts that the "front and rear portions" in Brunken clearly extend side by side along the entire length of the shaft. Applicant submits that there is a distinction between "portions" and "surfaces" and that the term "surface" should be accorded its ordinary meaning. At most, Brunken discloses two portions or sides of a needle shaft that extend side-by-side along the shaft – a front portion/side and a rear portion/side. However, this is not equivalent to having two visually distinct surfaces that extend along the shaft, wherein at least one of the surfaces is defined by the visual indicator.

Accordingly, Applicant respectfully submits that independent claim 1 patently defines over Brunken for at least the reason that Brunken fails to disclose, teach, or suggest the features emphasized above in claim 1.

Independent Claim 1 is Patentable Over Matsutani

Regarding the Matsutani reference, the Office alleges on page 6 in the Reponse to Arguments section that the Matsutani reference discloses a visual indicator on a needle that differentiates with a color between the inner and outer portions of the needle along its shaft. In alleging that the Matsutani reference teaches the features of claim 1, the Office Action refers to FIGS. 12-16 and specifically to "band 4" in FIG. 16. The Office Action further alleges that *"it would be obvious to extend these visual indicators along the entire shaft in order to aid a surgeon in recognizing the orientation of the needle at the distal tip (columns 10-11.)"* However, Applicant respectfully disagrees and submits that it would not have been obvious to extend the visual indicator (*i.e.*, "band 4" as referred to by the Office Action) along the entire shaft of the needle.

Applicant maintains that the welded portion (4) cited by the Office Action is not the same as the shaft recited in claim 1. It should be noted that the Office Action fails to address this argument in the Response to Arguments section. As emphasized by the Applicant in the prior response, the welded portion (4) of Matsutani is a separate component than the needle member (1). The needle member (1) and the pipe member (2) are formed of austenitic stainless steel and are welded together, resulting in the welded portion (4). It would not "have been obvious to extend the visual indicator (*i.e.*,

the welded portion (4)) along the entire shaft," as alleged by the Office Action. The Matsutani reference clearly makes the distinction between the welded portion (4) and the needle member (1). Indeed, the Abstract of the Matsutani reference states (emphasis added):

In a surgical needle, marks of welding are left as they are on a welded portion between needle and pipe members so that the welded portion has a surface distinguishable from peripheral surfaces of the respective needle and pipe members.

Applicant also submits that it would not be obvious to extend the welded portion down the length of the shaft because the purpose of the welding portion (4) is not to visibly distinguish between the front surface and the rear surface of the needle. Rather, the Matsutani reference teaches the following (emphasis added):

The ring-like welded portion 4 serves as a mark when, for example, the pipe member 2 is staked, so that it can be ensured that a part (designated by the character 2a in FIG. 5) of the pipe member 2 spaced a predetermined distance from the welded portion 4 is staked. This makes it possible to prevent occurrence of cracks or the like in the pipe member 2 due to staking of the welded portion 4 or a part very close thereto. Moreover, the ring-like welded portion 4 serves also as a mark by which when a doctor clamps the surgical needle with a chuck jig at a surgical operation, he can clamp the surgical needle while keeping away from the pipe member 2 which is low in strength.

Col. 7, lines 17-30.

In response to the allegation that it would have been obvious to extend the visual indicator (*i.e.*, welded portion (4)) down the entire length of the shaft, the Matsutani reference specifically teaches how the welding is carried out with respect to only predetermined angular extents along the abutting line 3 (in FIG. 7) (emphasis added):

In each of embodiments shown respectively in FIGS. 12 through 15,

welding is carried out with respect only to predetermined angular extents along the abutting line 3, in order to enable a surgical needle to have an especial function.

Col. 10, lines 11-15. Therefore, if anything, Matsutani appears to teach away from extending the welding portion down the entire length of the needle. The U.S. Court of Appeals for the Federal Circuit has stated that "[t]he mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992) (citing *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984)) (emphasis added).

Even assuming, *arguendo*, that the welded portion of the Matsutani reference is equivalent to the visual indicator in claim 1 (which it is not), it would not have been obvious to extend the welded portion taught by Matsutani along the entire shaft, as alleged by the Office Action. For at least the reasons described above, Matsutani fails to disclose, teach, or suggest the limitations, "wherein the shaft is marked at least partially with a visual indicator which defines one of a front surface and a rear surface," and "wherein the front surface and the rear surface extend side-by-side along the shaft," as recited in claim 1. Accordingly, Applicant respectfully submits that independent claim 1 patentably defines over Matsutani for at least the reason that Matsutani fails to disclose, teach, or suggest the features emphasized above in claim 1.

Independent Claim 11 is Patentable Over Brunken

Claim 11, as amended, recites (emphasis added):

11. A suture needle comprising:

a puncture tip; and
a shaft extending from the puncture tip, the shaft including
**means for distinguishing between a front surface of the shaft
and a rear surface of the shaft, wherein the front surface and
the rear surface extend side-by-side along the shaft.**

In the "Response to Arguments" section, the Office Action states that "Applicant argues that Brunken does not teach a suture needle with two surfaces that extend side-by-side along at least a portion of the shaft. This is not convincing because the front and rear portions disclosed clearly extend side by side along the entire length of the shaft (see Figure 1)." However, contrary to the assertions by the Examiner, Brunken fails to teach of "means for distinguishing between a front surface of the shaft and a rear surface of the shaft, wherein the front surface and the rear surface extend side-by-side along the shaft." Applicant, in fact, points out that the Office Action asserts that the "front and rear portions" in Brunken clearly extend side by side along the entire length of the shaft. Applicant submits that there is a distinction between "portions" and "surfaces" and that the term "surface" should be accorded its ordinary meaning. At most, the figures in Brunken depict two portions or sides of a needle shaft that extend side-by-side along the shaft – a front portion/side and a rear portion/side. This is not equivalent to having two visually distinct surfaces that extend along the shaft.

Applicant maintains that Brunken teaches of different zones or sections and does not teach a suture needle comprised of two surfaces that extend side-by-side along the shaft. The first zone/section consists of bare or untreated metal, while the surface of the remaining section of the needle is matt-finished or coloured. This is clearly illustrated in FIG.1 of the Brunken reference. See Brunken, zone (8) and section (10) in FIG. 1, reproduced on p. 9, *supra*. Accordingly, Applicant respectfully submits

that independent claim 1 patently defines over Brunken for at least the reason that Brunken fails to disclose, teach, or suggest the features emphasized above in claim 11.

Independent Claim 11 is Patentable Over Matsutani

Regarding the *Matsutani* reference, *Matsutani* fails to teach the feature, "a shaft extending from the puncture tip, the shaft including means for distinguishing between a front surface of the shaft and a rear surface of the shaft, wherein the front surface and the rear surface extend side-by-side along the shaft." Applicant maintains that the molded portion (4) referred to by the Office Action is not actually part of the needle member itself. The welded portion, pipe member and needle member are all clearly distinguished within the text (See, e.g., Abstract of *Matsutani* reference; "In a surgical needle, marks of welding are left as they are on a welded portion between needle and pipe members so that the welded portion has a surface distinguishable from peripheral surfaces of the respective needle and pipe members").

In response to the allegation that it would have been obvious to extend the visual indicator (i.e., welded portion (4)) down the entire length of the shaft, the *Matsutani* reference specifically teaches how the welding is carried out with respect to only predetermined angular extents along the abutting line 3. See *Matsutani*, FIG. 7. Accordingly, Applicant respectfully submits that independent claim 11 patently defines over *Matsutani* for at least the reason that *Matsutani* fails to disclose, teach, or suggest the features emphasized above in claim 11.

Independent Claim 20 is Patentable Over Brunken

Claim 20, as amended, recites (emphasis added):

20. A method of making a suture needle, comprising the steps of:
 providing a suture needle; and
 marking at least a portion of the suture needle with a visual indicator, wherein the portion extends at least partially the length of the suture needle, wherein the step of marking a portion of the suture needle comprises marking a surface of a shaft of the needle chosen from a front surface and a rear surface, wherein the front surface is the surface inside a curve of a shaft of the suture needle, and **wherein the rear surface is the surface outside the curve of the shaft of the suture needle.**

In the Response to Arguments section, the Office Action states that "[s]ince Applicant does not define the rear surface, it is reasonable to interpret this to mean that the front surface is also on the outside curve . . ." (Office Action, page 6). In an effort to further prosecution, Applicant has amended claim 20 to further clarify the relationship between the front surface and the rear surface. Applicant further submits that no new subject matter is added by the amendment.

In rejecting claim 20 on page 4, the Office Action alleges that Brunken discloses that "[t]he inside curve of the needle is marked with a visual indicator (see Figure 1 and page 2, lines 29-34)." Brunken, however, fails to teach that the front surface is the surface inside a curve of a shaft of the suture needle, and the rear surface is the surface outside the curve of the shaft of the suture needle (as defined by the clarifying amendment). As such, Brunken fails to teach the limitation, "wherein the step of marking a portion of the suture needle comprises marking a surface of a shaft of the needle chosen from a front surface and a rear surface."

In this regard, Applicant respectfully submits that independent claim 20 patently defines over Brunken for at least the reason that Brunken fails to disclose, teach, or suggest the features emphasized above in claim 20.

Dependent Claims 2, 3, 5-10, and 12-14 are Patentable

Applicant submits that dependent claims 2, 3, 5-10, and 12-14 are allowable for at least the reason that these claims depend from an allowable independent claim. See, e.g., *In re Fine*, 837 F. 2d 1071 (Fed. Cir. 1988).

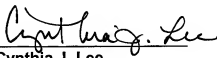
Additionally and notwithstanding the foregoing reasons for the allowability of their corresponding independent claims, these dependent claims recite further features/steps and/or combinations of features/steps, as apparent by examination of the claims themselves, that are patentably distinct from the prior art of record. Hence, there are other reasons why these dependent claims are allowable.

CONCLUSION

In light of the foregoing amendments and for at least the reasons set forth above, Applicant respectfully submits that all objections and/or rejections have been traversed, rendered moot, and/or accommodated, and that the now pending claims are in condition for allowance. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested.

Any other statements in the Office Action that are not explicitly addressed herein are not intended to be admitted. In addition, any and all findings of inherency are traversed as not having been shown to be necessarily present. Further, any and all findings of well-known art and official notice, or statements interpreted similarly, should not be considered well known for at least the specific and particular reason that the Office Action does not include specific factual findings predicated on sound technical and scientific reasoning to support such conclusions. If, in the opinion of the Examiner, a telephone conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (770) 933-9500.

Respectfully submitted,


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